4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 524

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Change of Sponsor; Change of Sponsor Address; Azaperone; Miconazole, Polymyxin B, and Prednisolone Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two new animal drug applications (NADAs) from Janssen Pharmaceutica NV, to Elanco Animal Health, a Division of Eli Lilly & Co. FDA is also amending the animal drug regulations to reflect a change of sponsor's address for Veterinary Service, Inc.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 115-732 for STRESNIL (azaperone) Injection and NADA 141-298 for SUROLAN (miconazole nitrate, polymyxin B sulfate, prednisolone acetate) Otic Suspension to Elanco Animal Health, a Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285. Following these changes of sponsorship, Janssen Pharmaceutica NV will no longer be the sponsor of an approved application. Accordingly, the Agency is amending the regulations in 21 CFR 510.600, 522.150, and 524.1445 to reflect the transfer of ownership.

In addition, Veterinary Service, Inc., 416 North Jefferson St., P.O. Box 2467, Modesto, CA 95354 has informed FDA of a change of address to 4100 Bangs Ave., Modesto, CA 95356. Accordingly, the Agency is amending the regulations in 21 CFR 510.600 to reflect these changes.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary

Medicine, 21 CFR parts 510, 522, and 524 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In § 510.600, in the table in paragraph (c)(1), remove the entry for "Janssen Pharmaceutica NV" and revise the entry for "Veterinary Service, Inc."; and in the table in paragraph (c)(2), remove the entry for "012758" and revise the entry for "033008" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Veterinary Service, Inc., 4100 Bangs Ave., Modesto, CA 95356	033008
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
033008	Veterinary Service, Inc., 4100 Bangs Ave., Modesto, CA 95356
* * * * *	

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.150 [Amended]

4. In paragraph (b) of § 522.150, remove “012578” and in its place add “000986”.

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

6. In § 524.1445, revise paragraph (b) to read as follows:

§ 524.1445 Miconazole, polymixin B, and prednisolone suspension.

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(b) Sponsor. See No. 000986 in § 510.600(c) of this chapter.

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Dated: August 1, 2012

Elizabeth Rettie,

Deputy Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

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